

## ARTICLE 3B. CLINICAL LABORATORIES

### **45:9-42.26. Short title**

This act shall be known and may be cited as the “New Jersey Clinical Laboratory Improvement Act.”

L.1975, c. 166, § 1, eff. Aug. 1, 1975.

### **Historical and Statutory Notes**

#### **Effective Dates**

L.1975, c. 166, § 23, approved July 23, 1975, provides:

“This act shall take effect the first day of the month following enactment, but all actions necessary and appropriate to enable this act to become effective on said date may be taken as though this act were effective immediately.”

#### **Title of Act:**

An Act concerning clinical laboratories, providing for the regulation thereof, amending § 22 and repealing §§ 16, 17 and 19 of P.L.1953, c. 420, L.1975, c. 166.

### **Administrative Code References**

Clinical laboratories, see N.J.A.C. 8:45-1.1 et seq.

Standards concerning testing and diagnostic centers, see N.J.A.C. 13:35-2.5.

State sanitary code, see N.J.A.C. 8:44-1.1 et seq.

### **Library References**

#### **American Digest System**

Physicians and surgeons; constitutional and statutory provisions, see Physicians and Surgeons ∇ 2.

#### **Encyclopedias**

Right to practice medicine, surgery, or other related callings in general; regulation or prohibition, see C.J.S.

Physicians, Surgeons, and Other Health-Care Providers § 7.

#### **WESTLAW Research**

Physicians and surgeons cases: 299k[add key number].

## **45:9-42.27. Definitions**

As used in this act:

- a. “Clinical laboratory” means any facility used for the performance of chemical, bacteriologic, virologic, parasitologic, serologic, hematologic, immuno-hematologic, biophysical, cytologic or other examinations of materials derived from the human body for the purpose of yielding information for the diagnosis, prevention or treatment of disease or the assessment of medical condition. Anatomic pathology is not considered to be within the scope of this definition. Any facility used for the collection, processing and transmission of specimens to another facility for the performance of clinical tests falls within the purview of this act.
- b. “Department” means the State Department of Health.
- c. “Commissioner” means the State Commissioner of Health or his duly authorized agent.
- d. “Clinical laboratory owner” means a person or agency in whom is vested the rights of control, possession, and dominion of a clinical laboratory and for the purposes of this act shall include a county, municipality, or any other owner of an institution operating a clinical laboratory.
- e. “Clinical laboratory director” means a person who is responsible for the administration of the technical and scientific operation of a clinical laboratory, including, but not limited to, supervision of procedures for testing and reporting of results. Nothing in this act shall be deemed to exempt the director of a clinical laboratory from the licensure requirements of P.L.1953, c. 420 (C. 45:9-42.1 et seq.), where such requirements would otherwise be applicable.
- f. “Clinical laboratory evaluation program” means a program of evaluating the proficiency of clinical laboratories by the department.
- g. “Anatomic pathology” means the gross or microscopic examination of tissues by a physician specifically trained to interpret and diagnose disease by such examination.
- h. “Person” means any individual, partnership, limited partnership, corporation or other legal entity.

L.1975, c. 166, § 2, eff. Aug. 1, 1975

## **Library References**

### **American Digest System**

Physicians and surgeons; capacity and qualifications, see Physicians and Surgeons ∇ 4.

Physicians and surgeons; constitutional and statutory provisions, see Physicians and Surgeons ∇ 2.

### **Encyclopedias**

Physicians and surgeons; capacity and qualifications, see C.J.S. Physicians, Surgeons, and Other Health-Care Providers § 19.

Right to practice medicine, surgery, or other related callings in general; regulation or prohibition, see C.J.S. Physicians, Surgeons, and Other Health-Care Providers § 7.

## **WESTLAW Research**

Physicians and surgeons cases: 299k[add key number].

### **45:9-42.28. License; necessity; categories**

No person shall conduct, maintain, or operate a clinical laboratory or solicit or accept specimens for laboratory examination unless a license therefor has been obtained from the department pursuant to the terms of this act. A separate license shall be obtained for each location. A clinical laboratory license shall be obtained for all or any designated part of any one or more of the following categories, or other categories as may be included in rules and regulations promulgated pursuant to this act:

- a. Microbiology, including the subcategories of bacteriology, virology, mycology, and parasitology;
- b. Serology, including syphilis serology, nonsyphilis serology;
- c. Hematology, including immunohematology; and,
- d. Clinical chemistry, including urinalysis, chemical toxicology, and in vitro radioisotope technic.

L.1975, c. 166, § 3, eff. Aug. 1, 1975.

## **Historical and Statutory Notes**

**Prior Laws:** C. 45:9-42.16 (L.1953, c. 420, p. 2106, § 16).

## **Library References**

### **American Digest System**

Physicians and surgeons; registration, certificate, or license, see Physicians and Surgeons V5(1) et seq.

### **Encyclopedias**

Physicians and surgeons; license, certificate, or registration, see C.J.S.

Physicians, Surgeons, and Other Health-Care Providers § 11 et seq.

## **WESTLAW Research**

Physicians and surgeons cases:  
299k[add key number].

#### **45:9-42.29. License; application; form; contents; fee; annual renewal**

All clinical laboratories operating prior to the effective date of this act shall be issued a license upon submission of a properly completed application form and payment of the requisite fee. Said license shall thereafter be renewable, on a calendar year basis, subject to all provisions of this act. The license application form shall include, but need not be limited to the following information:

- a. The name and address of the clinical laboratory owner and his authorized agent and such information regarding the owner and agent as may be required;
- b. The name and address of the clinical laboratory director;
- c. The name and address of the clinical laboratory for which the license is requested and a description and plan of the premises to be occupied for the operation of said laboratory;
- d. A list of the major laboratory equipment to be utilized; and,
- e. The tests to be performed in the clinical laboratory.

L.1975, c. 166, § 4, eff. Aug. 1, 1975.

#### **Cross References**

Charges for examinations, licensures and other services, establishment or change by rule, see §45:1-3.2.

#### **Library References**

##### **American Digest System**

Physicians and surgeons; registration, certificate, or license, see Physicians and Surgeons ∇5(1) et seq.

##### **Encyclopedias**

Physicians and surgeons; license, certificate, or registration, see C.J.S.

Physicians, Surgeons, and Other Health-Care Providers § 11 et seq.

##### **WESTLAW Research**

Physicians and surgeons cases:  
299k[add key number].

#### **45:9-42.30. Annual issuance and expiration; renewal; fees; display**

All clinical laboratory licenses shall be issued on or before January 1 in each calendar year and shall expire on December 31 in each calendar year. Application for renewal therefor shall be made at such time and in such manner as shall be prescribed by the department. The commissioner shall charge for a license or renewal such reasonable fees as he shall prescribe by

rule or regulation. The license shall be conspicuously displayed by the licensee on the premises of a clinical laboratory.

L.1975, c. 166, § 5, eff. Aug. 1, 1975.

### **Historical and Statutory Notes**

**Prior Laws:** C. 45:9-42.17 (L.1953, c. 420, p. 2107, § 17).

### **Cross References**

Charges for examinations, licensures and other services, establishment or change by rule, see § 45:1-3.2.

### **Library References**

#### **American Digest System**

Licenses for occupations and privileges; license fees and taxes, see Licenses ∇27.

#### **Encyclopedias**

License fees and taxes, see C.J.S. Licenses § 64 et seq.

#### **WESTLAW Research**

Licenses cases: 238k[add key number].

### **45:9-42.31. Owner and director; joint and separate responsibility for compliance**

The owner and director of a clinical laboratory shall be jointly and separately responsible for its compliance with this act and regulations as may be promulgated hereunder.

L.1975, c. 166, § 6, eff. Aug. 1, 1975.

### **Library References**

#### **American Digest System**

Physicians and surgeons; regulation of professional conduct, see Physicians and Surgeons ∇10.

## **Encyclopedias**

Physicians and surgeons; regulation  
of professional conduct, see C.J.S.

Physicians, Surgeons, and Other Health-  
Care Providers § 53 et seq.

## **WESTLAW Research**

Physicians and surgeons cases:  
299k[add key number].

### **45:9-42.32. Transfer of license; prohibition; change in ownership or direction; notice and reapplication**

No license issued under the provisions of this act shall be transferable. A change in ownership or direction of a licensed laboratory shall require notification to the department within 14 calendar days and reapplication for licensure.

L.1975, c. 166, § 7, eff. Aug. 1, 1975.

## **Library References**

### **American Digest System**

Physicians and surgeons; registration,  
certificate, or license, see Physicians  
and Surgeons ∇ 5(1) et seq.

## **Encyclopedias**

Physicians and surgeons; license cer-  
tificate, or registration, see C.J.S.

Physicians, Surgeons, and Other Health-  
Care Providers § 11 et seq.

## **WESTLAW Research**

Physicians and surgeons cases:  
299k[add key number].

### **45:9-42.33. Exemptions from act**

The provisions of this act shall not apply to:

- a. Clinical laboratories operated and maintained exclusively for research and teaching purposes, involving no patient or public health services whatsoever;
- b. Clinical laboratories operated by the United States Government, or blood banks licensed under P.L.1963, c. 33 (C.26:2A-2 et seq.);
- c. Clinical laboratories specifically exempted from the provisions of this act by rules and regulations promulgated by the Public Health Council pursuant to section 9 of P.L.1975, c. 166 (C45:9-42.34); or
- d. Clinical laboratories which are operated by the Department of Corrections, any county jail, any county probation department, or any drug or alcohol treatment center providing services to persons under the jurisdiction of any of these agencies or in a programs of supervisory treatment center providing services to persons supervisory treatment pursuant to the provisions of N.J.S.2C:43-13 and which perform only urinalysis for screening purposes to detect the presence of alcohol or illegal substances. The Attorney General shall approve procedures, methods and devices used by these agencies or centers in screening for alcohol or illegal substances.

L.1975, c. 166, § 8, eff. Aug. 1, 1975. Amended by L.1991, c. 26, § 1, eff. Feb. 19, 1991.

### **Senate Labor, Industry and Professions Committee Statement**

#### **Assembly, Nos. 3614 and 3557 ACS and Senate, No. 2757-L.1991, c. 26**

The Senate Labor, Industry and Professions Committee reports favorably a Senate Committee Substitute for Assembly, Nos. 3614 and 3557 (ACS) and Senate, No. 2757.

This bill exempts certain agencies from the licensing requirements of the “New Jersey Clinical Laboratory Improvement Act,” P.L.1975, c. 166 (C.45:9-42.26 et seq.). The bill exempts clinical laboratories which are operated by the Department of Corrections, any county jail, any county probation department, and any drug or alcohol treatment center providing services to persons under the jurisdiction of any of these agencies or in a program of supervisory treatment pursuant to the provisions of N.J.S. 2C:43-13 if they perform only urinalysis for screening purposes to detect the presence of alcohol or illegal substances. The Attorney General must approve procedures, methods and devices used by these agencies and centers in screening for alcohol or illegal substances.

The intent of the bill is to permit any of these agencies or centers to conduct alcohol or drug screening of inmates or certain other persons without the requirement of obtaining a clinical laboratory license.

### **Historical and Statutory Notes**

#### **Amendments**

- L.1991, c. 26, § 1, inserted “Clinical laboratories” at the beginning of subsecs.
- a. to c. and added subsec. d.

## Library References

### American Digest System

Physicians and surgeons; constitutional and statutory provisions, see Physicians and Surgeons ¶2.

### Encyclopedias

Right to practice medicine, surgery, or other related callings in general; regulation or prohibition, see C.J.S.

Physicians, Surgeons, and Other Health-Care Providers § 7.

### WESTLAW Research

Physicians and surgeons cases:  
299k[add key number].

### 45:9-42.34. Rules and regulations; operation of clinical laboratories; standards

The Public Health Council of the department shall promulgate rules and regulations for operation of clinical laboratories which shall be incorporated in and made a part of the State Sanitary Code. Where feasible such rules and regulations shall equal or exceed minimum standards for laboratory certification contained in Federal rules and regulations promulgated pursuant to the “Clinical Laboratories Improvement Act of 1967” (Public Law 90-174) 42 U.S.C. 263a. The rules and regulations so promulgated shall include but shall not be limited to standards for:

- a. Construction of new, or modification of existing clinical laboratories.
- b. Sanitary and safe conditions within the clinical laboratory and its surroundings, including adequate working space, lighting, fire prevention and safety measures.
- c. Clinical laboratory equipment, maintenance procedures for such equipment and personnel essential to proper conduct and operation of a clinical laboratory, including standards for education, experience, continuing education, and periodic proficiency testing for laboratory directors, supervisors, technicians, and other personnel which the department may deem necessary for adequate laboratory staffing.
- d. The acceptance, collection, transportation, identification and examination of clinical laboratory specimens and reporting of results by clinical laboratories.
- e. Reporting by laboratories of diseases for the protection of the public health. The department shall furnish forms for this purpose. Such reports shall not be construed as constituting a diagnosis nor shall any clinical laboratory making such report be held liable under the laws of the State for having violated a trust or confidential relationship.



- f. Submitting such reports concerning clinical laboratory operations as may be necessary to administer this act. Each laboratory shall maintain a manual of procedures followed in that laboratory, which shall be reviewed and updated annually. Such manual shall also include, but not be limited to, a list of equipment used for each procedure.

N.J.S.A. 45:1 to 45:11-23

- g. Exemptions of specific types of clinical laboratories from the provisions of section 7 of P.L.1971, c. 136 (C. 26:2H-7).

L.1975, c. 166, § 9, eff. Aug. 1, 1975.

### **Library References**

#### **American Digest System**

Physicians and surgeons, regulation of  
professional conduct, see Physicians  
and Surgeons ∇10.

#### **Encyclopedias**

Physicians and Surgeons, regulation of  
professional conduct in general, see  
C.J.S. Physicians, Surgeons, and

Other Health-Care Providers § 53 et seq.

#### **WESTLAW Research**

Physicians and surgeons cases:  
299k[add key number].

### **45:9-42.35. Rules and regulations; license application, issuance, renewal and expiration**

The commissioner shall establish reasonable rules and regulations for license application, issuance, renewal and expiration.

L.1975, c. 166, § 10, eff. Aug 1, 1975.

### **Library References**

#### **American Digest System**

Physicians and surgeons; registration,  
certificate, or license, see Physicians  
and Surgeons ∇5(1) et seq.

#### **Encyclopedias**

Physicians and surgeons, license, cer-  
tificate, or registration, see C.J.S.

Physicians and surgeons cases:  
299k[add key number].

**45:9-42.36. Advisory committee**

An advisory committee shall be appointed by the commissioner and shall serve for a term of 2 years, with no member serving for more than two consecutive terms. Members of the advisory committee shall serve in a voluntary capacity to advise the department on all matters relating to this act and shall consist of two persons who are diplomates of the American Board of Pathology, two directors of private clinical laboratories who are not pathologists, one physician who is not pathologist, one medical technologist, one private citizen not directly related to the practice of medicine or the operation of a clinical laboratory and such additional members as the commissioner may in his discretion appoint. Members shall serve without compensation but shall receive actual and necessary expenses.

L.1975, c. 166, § 11, eff. Aug. 1, 1975.

**Library References**

**American Digest System**

Physicians and surgeons; constitution-  
al and statutory provisions, see Phy-  
sicians and Surgeons V2.

**Encyclopedias**

Right to practice medicine, surgery, or  
other related callings in general;  
regulation or prohibition, see C.J.S.

Physicians, Surgeons, and Other Health-  
Care Providers § 7.

**WESTLAW Research**

Physicians and Surgeons cases:  
299k[add key number].

**45:9-42.37. Evaluation program**

The department shall establish and conduct a clinical laboratory evaluation program to:

- a. Prescribe minimum standards of performance in the examination of specimens;
- b. Test the proficiency of clinical laboratories to determine if minimum standards of performance are being met; and

- c. Develop and organize appropriate consultation and training activities in clinical laboratory procedures with the purpose of improving the quality of performance of clinical laboratories licensed by this act.

L.1975, c. 166, § 12, eff. Aug. 1, 1975

### **Library References**

#### **American Digest System**

Physicians and surgeons; regulation  
of professional conduct, see Physi-  
cians and Surgeons ∇10.

#### **Encyclopedias**

Physicians and surgeons; regulation  
of professional conduct, see C.J.S.

Health-Care Providers § 53 et seq.

Physicians, Surgeons, and Other

#### **WESTLAW Research**

Physicians and Surgeons cases:  
299k[add key number].

### **45:9-42.38. Right of entry and inspection**

The department and any officers or employees thereof in the performance of any duty imposed by this act shall have the power and authority to enter at any time and inspect any clinical laboratory for the purpose of studying and evaluating the operation, supervision, records, and procedures of such facilities and to determine their effect upon the health and safety of the people of the State.

L.1975, c. 166, § 13, eff. Aug. 1, 1975

### **Library References**

#### **American Digest System**

Physicians and surgeons; regulation  
of professional conduct, see Physi-  
cians and Surgeons ∇10.

#### **Encyclopedias**

Physicians and surgeons; regulation

of professional conduct, see C.J.S.

Physicians, Surgeons, and Other  
Health-Care Providers § 53 et seq.  
**WESTLAW Research**

Physicians and Surgeons cases:  
299k[add key number].  
**45:9-42.39. Confidentiality of information, examination upon application to court**

All reports submitted under the provisions of this act and any information obtained in the course of inspections shall be deemed confidential and may be examined only upon application to a court of competent jurisdiction in association with proceedings related to suspension, limitation, or revocation of a license under this act. This provision shall in no way interfere with the department's powers to summarize, analyze and publish information obtained during the course of carrying out provisions of this act so long as the specific identity of individual laboratories is not disclosed, nor shall it be considered to limit the department's powers in disclosing results of an action in suspending, limiting or revoking a license of a specific laboratory under the provisions of this act.

L.1975, c. 166, § 14, eff. Aug. 1, 1975.

### **Law Review Commentaries**

Access to medical records. Robert J.  
Conroy, Mark D. Brylski, and Kathy Op-  
erman, 118 N.J.Law. 32 (Feb. 1987).

### **Library References**

#### **American Digest System**

Physicians and surgeons; regulation of  
professional conduct, see Physicians  
and Surgeons ¶10.

#### **Encyclopedias**

Physicians and surgeons; regulation of  
professional conduct, in general, see  
C.J.S. Physicians, Surgeons, and Oth-

er Health-Care Providers § 53 et  
seq.

#### **WESTLAW Research**

Physicians and Surgeons cases:  
299k[add key number].

#### **45:9-42.40. Denial, revocation, suspension, limitation, annulment or denial of renewal; grounds**

A clinical laboratory license may be denied, revoked, suspended, limited, annulled, or renewal thereof may be denied by the commissioner for good cause, including but not limited to:

- a. Making false statements on an application for a clinical laboratory license or any other documents required by the department.
- b. A reasonable finding by the department that the quality of performance of clinical laboratory tests is below those set by the department and that remedial measures such as consultation and training are not accepted or do not result in improvement to a level of proficiency acceptable to the department.
- c. Reporting of fictitious results not based on test performance.
- d. Performing a test and rendering a report thereon to a person not authorized by law to receive such services.
- e. Referring a specimen for examination to an unlicensed clinical laboratory that is required to be licensed under this act.
- f. Knowingly having professional connection with or lending the use of the name of the licensed clinical laboratory to an unlicensed clinical laboratory;
- g. Violating or aiding and abetting in the violation of any provision of this act or the provisions of the State Sanitary Code<sup>1, 2</sup>.
- h. Failing to file any report required by the provisions of this act or the provisions of the State Sanitary Code.
- i. Representing that the laboratory is entitled to perform any laboratory procedure or category of procedures not authorized in its license.

L.1975, c. 166, § 15, eff. Aug. 1, 1975.

<sup>1</sup> Establishment of State Sanitary Code, see § 26:1A-7.

<sup>2</sup> So in enrolled bill.

#### **Library References**

##### **American Digest System**

Physicians and surgeons capacity and qualifications, see Physicians and Surgeons ∇ 4.

##### **Encyclopedias**

License, certificate, or registration of physicians and surgeons; qualification of applicant and proof thereof,

see C.J.S. Physicians, Surgeons, and Other Health-Care Providers § 19 et seq.

##### **WESTLAW Research**

Physicians and Surgeons cases:  
299k[add key number].

**45:9-42.41. Refusal to grant, suspension, limitation or revocation of license; notice; hearing; service of order; summary suspension**

The commissioner, before refusing to grant a license or before suspending, limiting or revoking a license previously granted shall give notice to the applicant or licensee personally, or by mail addressed to him at his last known address, and afford him an opportunity to be heard with respect thereto at a time and place specified in such notice. Such applicant or licensee shall have the right to be heard in person or through an attorney, and to offer evidence pertinent to the subject of the hearing. A duly certified copy of the order of the commissioner issued as a result of such hearing shall be served on the applicant or the licensee by mail personally addressed to him at his last known address, except if such applicant or licensee be a corporation then the order shall be served in the same manner upon any officer or registered agent of the corporation.

If the commissioner shall have reason to believe that a condition exists or has occurred at a laboratory, in violation of the provisions of this act or the rules and regulations promulgated hereunder, which condition poses an imminent threat to the public health, safety or welfare, he may summarily suspend the license of the laboratory without a hearing and may order immediate correction of such violation as a prerequisite of reinstatement of licensure. If a licensee that is subjected to summary suspension shall deny that a violation exists or has occurred, he shall have the right to apply to the commissioner for a hearing. Such hearing shall be held and a decision rendered within 48 hours or <sup>1</sup> receipt of said request. If the commissioner shall rule against the licensee, the licensee shall have the right to apply for injunctive relief against the commissioner's order. Jurisdiction of such injunctive relief shall be in the Superior Court of New Jersey.

L.1975, c. 166, § 16, eff. Aug. 1, 1975.

<sup>1</sup> So in enrolled bill. Probably should be "of".

**Library References**

**American Digest System**

Physicians and surgeons capacity and qualifications, see Physicians and Surgeons ∇ 4.

State government and officers; authority and powers of executive de-

partments, boards, or other bodies, see States ∇ 67.

**Encyclopedias**

License, certificate, or registration of physicians and surgeons; qualification of applicant and proof thereof, see C.J.S. Physicians, Surgeons, and Other Health-Care Providers § 19 et seq.

State government and officers; powers, functions, and duties of particu-

lar officers, boards, departments, and functionaries, see C.J.S. States § 136 et seq.

State government and officers; powers, privileges, duties, and liabilities of officers, agents, and employees,

See C.J.S. States §§ 120 et seq.

## **WESTLAW Research**

Physicians and Surgeons cases:

299k[add key number].

States cases: 360k[add key number].

### **45:9-42.41a. Clinical laboratories; presentment of bills or claims for payment**

A clinical laboratory shall present or cause to be presented a claim, bill or demand for payment for clinical laboratory services directly to the recipient of the services, except that the claim, bill or demand for payment may be presented to any of the following:

- a. An immediate family member of the recipient of the services or other person legally responsible for the debts or care of the recipient of the services;
- b. A third party payer including a health insurer, a health, hospital or medical services corporation, a State approved or federally qualified health maintenance organization in which the recipient of the services is enrolled, a governmental agency or its specified agent which provides health care benefits on behalf of the recipient of the services, and an employer of the recipient of the services who is responsible for payment of the services, provided that billing these payers is consistent with the terms of any applicable contract between the payer and the recipient of the services;
- c. A hospital or skilled nursing facility in which the recipient of the services is or has been an inpatient or outpatient;
- d. A substance abuse program in which the recipient of the services is or has been a participant; and
- e. A nonprofit clinic or other health care provider whose purpose is the promotion of public health, from which the recipient of the services has received health care.

Upon the request of the health care provider who requested the clinical laboratory services, a clinical laboratory shall notify the health care provider of the amount of the claim, bill or demand for payment that was presented to the recipient or the recipient's responsible third party pursuant to this section.

Notwithstanding the provisions of this section to the contrary, in the case of a clinical laboratory which performs services at the request of another clinical laboratory, the clinical laboratory may present the claim, bill or demand for payment to the requesting clinical laboratory.

Notwithstanding the provisions of this section to the contrary, nothing in this section shall affect a contractual agreement between a clinical laboratory and a third party payer regarding presentation of a claim, bill or demand for payment directly to that third party payer.

L.1997, c. 156, § 1, eff. July 3, 1997.

**45:9-42.41b. Clinical laboratories; list of fees and charges to be provided to health care providers annually**

A clinical laboratory shall annually provide a health care provider with a list of its schedule of fees and charges for laboratory services rendered to the health care provider's patients. The clinical laboratory shall promptly provide the health care provider with an updated list of its schedule of fees and charges whenever any changes are made to the list. The clinical laboratory shall include with the list a form to be used by the health care provider to request billing information pursuant to section 1 of this act.

L.1997, c. 156, § 4, eff. July 3, 1997.

**45:9-42.41c. Fees for interpretation of laboratory test results**

Nothing in this act shall be construed to prevent a health care provider from including a charge for the interpretation of a laboratory test as part of the health care provider's office visit fee.

L.1997, c. 156, § 5, eff. July 3, 1997.

**45:9-42.42. Prohibited activities**

No person shall:

- a. Operate, maintain, direct, or engage in the business of operating a clinical laboratory, as herein defined, unless he has obtained a clinical laboratory license from the department, or is exempt under the provisions of this act.
- b. Collect or receive specimens for analysis by an unlicensed laboratory.
- c. Accept specimens for tests from and make reports to persons who are not legally qualified or authorized to submit specimens to clinical laboratories and to receive such reports, but this shall not prohibit the referral of specimens from one licensed clinical laboratory to another similarly licensed under the laws of the state in which it is located, providing the report indicates clearly the clinical laboratory performing the test and the name of the director of such clinical laboratory.
- d. Either personally, or through an agent, solicit referral of specimens to his or any other clinical laboratory or contract to perform clinical laboratory examinations of specimens in a manner which offers or implies an offer of rebates to a person or persons submitting specimens, other fee-splitting inducements, participation in any fee-splitting arrangements or other unearned remuneration.



e. Obstruct or interfere with the department of any officer or employee thereof in the performance of any duty imposed by this act.

f. Collect any amounts that were billed in violation of section 1 of P.L. 1997, e. 156 (C.45:9-42.41a).

Amended by L.1997, c. 156, § 2, eff. July 3, 1997.

L.1975, c. 166, § 17, eff. Aug. 1, 1975

### **Historical and Statutory Notes**

**Prior Laws:** C. 45:9-42.19 (L.1953, c. 420, p. 2107, § 19).

### **Library References**

#### **American Digest System**

Physicians and surgeons regulation of  
professional conduct, see Physicians  
and Surgeons ∇ 10.

#### **Encyclopedias**

Physicians and surgeons; regulation of  
professional conduct in general, see  
C.J.S. Physicians, Surgeons, and Ot-

her Health-Care Providers § 53 et seq.

#### **WESTLAW Research**

Physicians and surgeons cases:  
299k[add key number].

#### **45:9-42.43. Violations; penalty**

a. Any person convicted of violating any provision of this act or of any rule or regulation adopted hereunder shall be subject to a penalty of not less than \$100.00 nor more than \$1000.00 for each violation. The penalty shall be collected, and enforced in summary proceedings under the Penalty Enforcement Law (N.J.S.2A:58-1 et seq.).

b. A person who collects any amounts that were billed in violation of section 1 of the P.L. 1997, c. 156 (C.45:9-42.41a), is liable for, and shall refund on a timely basis to the person who was billed, any amounts so collected.

Amended by L.1997, c. 156, § 3, eff. July 3, 1997.

### **Notes of Decisions**

## Penalties 1

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### 1. Penalties

Clinical laboratory's failure to produce instrument printouts needed to substantiate reported test results, failure to take corrective action when test systems produced inaccurate results, failure to ensure

correct patient specimen identification, failure to ensure integrity of patients' specimens, failure to report test results, and failure to provide normal range when reporting test results warranted revocation of license; \$8,000 penalty also assessed against laboratory owner. Scientific Diagnostic Laboratories, Inc. v. Department of Health, State of N.J., 92 N.J.A.R.2d(HLT)21(1992).

L.1975, c. 166, § 18, eff. Aug. 1, 1975.

## Library References

### American Digest System

Physicians and surgeons, regulation of professional conduct, see Physicians and Surgeons ∇ 10.

### Encyclopedias

Physicians and Surgeons, regulation of professional conduct in general, see C.J.S. Physicians, Surgeons, and

Other Health-Care Providers § 53 et seq.

## WESTLAW Research

Physicians and surgeons cases:  
299k[add key number].

### 45:9-42.44. Injunction of violation or threatened violation

Any violation or threatened violation of any provision of this act or of any rule or regulation adopted hereunder may be restrained by the Superior Court in an action brought for such purpose by the Attorney General on behalf of the department.

L.1975, c. 166, § 19, eff. Aug. 1, 1975.

## Library References

### American Digest System

Subjects of protection and relief; un-

authorized business and professional activity, see Injunction ∇ 89(5).

### **Encyclopedias**

Subjects of protection and relief; illegal practice of law, medicine, and allied

professions, see C.J.S. Injunctions § 135 et seq.

### **WESTLAW Research**

Injunction cases: 212k[add key number].

### **45:9-42.45. Severability**

If any provision of this act, or any application of any provision, is held invalid, the invalidity shall not affect other applications of the provision, or other provisions of the act, which reasonable can be given effect despite the invalidity. To this end, the provisions of this act are hereby declared severable.

L.1975, c. 166 § 20, eff. Aug. 1, 1975.

## **Library References**

### **American Digest System**

Effect of partial invalidity of statutes in general, see Statutes ∇ 64(1).

### **Encyclopedias**

Effect of partial invalidity of statute in general, see C.J.S. Statutes § 92.

### **WESTLAW Research**

Statutes cases: 361k[add key number].